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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/406,473	09/27/1999	STEPHEN D. PACETTI	M-7395US	1646

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CAMERON KERRIGAN  
SQUIRE, SANDERS & DEMPSEY LLP  
ONE MARTINE PLAZA  
SUITE 300  
SAN FRANCISCO, CA 94111-3492

EXAMINER

THANH, LOAN H

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 11/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

# Office Action Summary

Application No.

09/406,473

Applicant(s)

PACETTI, STEPHEN D.

Examiner

LoAn H. Thanh

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) 11-47 and 61-63 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-8, 56-58, 64, 65, 69 and 70 is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 9, 10, 48-51, 54, 55, 59, 60, 66-68 and 71-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-5, 48-51,54-55, 66-68,71-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian et al. (U.S. Patent No. 5,674,192).

Sahatjian et al. disclose a medical kit comprising a coated stent deployed by a balloon catheter wherein the stent is coated with a therapeutic substance . Further, it is disclosed that the sheath is made of polyethylene, polyurethane, TEFLON or TECOFLEX. Sahatjian et al. teach the sheath is for protecting the drug/coating and for inhibiting premature release of the drug. The protective sheath is for preventing the release of the drug prior to reaching the desired location in the body. See col. 1-3, 8, 10-11, 14. It is inherent that the materials of the Sahatjian have the oxygen transmission rate as evidenced by Marotta ( Packaging Forum).

Claims 71-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Yurek et al. ( U.S. Patent No. 5,662,703).

Yurek et al. disclose a sheath for covering an implantable medical device (stent), the sheath (26 – 46-48) comprising a hollow body made of a material such as a compatible thermoplastic elastomer ( polyurethane, polyethylene, nylon and their copolymers). Applicant has positively claimed the medical device carrying the

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therapeutic substance. With respect to the functional limitation of the material preventing the substance significantly diffusing out from the device, it is considered to be capable of performing the function. "significantly diffusing" is considered to be a relative term. Further, it is considered to be capable of performing the "prevention of significantly diffusing" since the materials disclosed by the prior art is the same.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-10, 59-60, 75-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahatjian et al. (U.S. Patent No. 5,674,192).

Sahatjian et al. teach all the limitations of the claims except for materials such as polyester (PET, etc.) or polyamides (nylon-6 etc.). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Further, it would have been obvious to modify the material to a specific species of the material in order to

decrease manufacturing cost of the material which is more readily available commercially which also produce the same result.

Claims 75-78 are rejected under 35 U.S.C. 103(a) as obvious over Pinchuk et al. ( U.S. Patent No. 5,700,269).

Pinchuk et al. disclose a sheath ( 56) for covering an implantable medical device comprising a tubular hollow body comprising a layer made of polyester or polyamide. However, Pinchuk et al. does not disclose the specific species of the polyester or polyamide material such as polyethylene terephthalate or nylon -6, etc. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute different species of the polyester or polyamide materials as a mere design choice of materials in order to obtain desired properties of the sheath or to produced/manufacture the sheath at a lower cost with a more commercially available materials.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-5,9-10,48-55,59-60 have been considered but are moot in view of the new ground(s) of rejection.

### ***Allowable Subject Matter***

Claims 6-8,56-58,64-65,69-70 are allowable since the prior art of record fails to teach or render obvious a medical kit comprising the combination of a stent having a therapeutic agent and a sheath wherein the sheath is limited to a tubular body which

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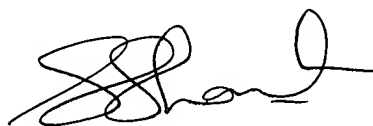
prevents the diffusion of the therapeutic material into the sheath or absorbing into the sheath by the material of the sheath as claimed in the respective claims.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Monday to alternating Fridays (7:00 am-4:30 pm).

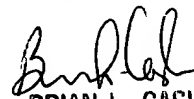
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



LoAn H. Thanh  
Examiner  
Art Unit 3763

LT  
October 30, 2002.



BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700